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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,919	09/01/2006	Jude A. Oben	OB080-0000B	1397
24350 7590 09/03/2008 STITES & HARBISON, PLLC 400 W MARKET ST SUITE 1800 LOUISVILLE, KY 40202-3352				
EXAMINER VAKILL, ZOHREH				
ART UNIT		PAPER NUMBER		
1614				
MAIL DATE		DELIVERY MODE		
09/03/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/550,919

Applicant(s)

OBEN ET AL.

Examiner

ZOHREH VAKILI

Art Unit

1614

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Claims 19-26 are presented for examination.

Applicant's Amendment filed April 14, 2008 has been received and entered into the present application. Claims 19-26 are pending and are herein examined on the merits.

Applicant's arguments, filed April 14, 2008 have been fully considered. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Claim Rejections - 35 USC § 112 (New Matter)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant adds new limitations to the claims

that raise the issue of new matter. New matter issues are raised when Applicant includes limitations in the claims that he/she clearly did not have possession of at the time of invention. The silence of the disclosure regarding **a method of treating a diet-induced fatty liver disease is a non-alcoholic fatty liver disease** is not sufficient to now claim the exclusion of such step because nowhere in the disclosure has Applicant discussed **a method of treating a diet-induced fatty liver disease is a non-alcoholic fatty liver disease** limitation in the context of the instant claims.

Claim Rejections - 35 USC § 102 (New Ground of rejection)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 19-21, 24-26 are rejected under 35 U.S.C. 102(b) as being anticipated by McLean (US Pat. No. 6174917).

McLean teaches a method for treatment of liver disease including cirrhosis, toxic and medicamentary liver damage, and other disorders with vasodilators given in column 3, lines 30-35, including in a short list, prazosin as instantly cited in instant claim 21 which thus anticipates the above listed instant claims. Dubuisson et al. (US Pat. No. 6,649,615) is cited herein to indicate evidence that prazosin is an adreno receptor

antagonist as disclosed in column 1, lines 45-48, thus supporting rejection of instant claims citing usage of such an antagonist. Further Dubuisson et al. at column 4, lines 1-12, discloses prazosin as an alpha-adrenoreceptor antagonist.

Claims 19-21, 24-26 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Dubuisson et al. (Pat. No. 6,649,615).

Dubuisson et al. (Pat. No. 6,649,615) discloses that prazosin is an adreno receptor antagonist as disclosed in column 1, lines 45-48, thus supporting rejection of instant claims citing usage of such an antagonist. Further Dubuisson et al. at column 4, lines 1-12, discloses prazosin as an alpha-adrenoreceptor antagonist. In the abstract of Dubuisson et al. the invention is directed to hepatic fibrogenesis treatment. Cirrhosis is cited as an endpoint of such fibrosis in col. 2, lines 60-63, and thus the reference teaches treatment inclusive of liver disorder as instantly claimed. Column 2, lines 45-59, cite other liver disorders including damaged liver as instantly claimed as being treated via the reference's pharmaceuticals. Prazosin is disclosed in the reference in column 2, lines 24-63, as utilized for treating liver disorders or damage as instantly claimed thus anticipating the above listed instant claims.

Claims 19 and 22-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Sonoke et al. (US Pat. No. 6544542 B1).

Sonoke et al. discloses of lipid-soluble drugs and water-insoluble drugs. Drugs which can be used for liver diseases (col. 2, lines 57-65). The following drugs can be mentioned by way of example. Such as beta-Adrenergic Agonists: isoprenaline, salts thereof, and their lipid-soluble derivatives (col. 3, lines 10-18).

Consequently, the reference anticipates the claimed invention defined in claim 19 and 22-26.

Applicant's amendments and remarks have been carefully considered in their entirety, but fail to be persuasive in establishing error in the propriety of the present rejection.

Conclusion

No claims of the present application are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zohreh Vakili whose telephone number is 571-272-3099. The examiner can normally be reached on 8:30-5:00 Mon.-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Zohreh Vakili

Patent Examiner 1614

August 28, 2008

/Ardin Marschel/

Supervisory Patent Examiner, Art Unit 1614